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House of Lords
London SW1A 0PW

ORGANIZATION: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

SUBJECT: House of Lords Science and Technology Select Committee Call for Evidence: Nanotechnologies and Food

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1. There is little doubt that nanotechnologies have an important role to play in the food sector. They have the potential to raise nutritional value, increase shelf life, decrease manufacturing costs, and prevent harm to consumers. These advances will benefit producers and consumers alike. But they do not come without raising the possibility of new potential risks to human health and the environment. As our abilities to construct and manipulate sophisticated materials at ever-smaller scales increase, the challenges of understanding and managing the full implications of these abilities multiply. Without a careful evaluation of emerging risks, and strategies for managing these risks, it is unlikely that the full benefits of nanotechnologies will be realized—whether in the food sector or the many other areas where the technologies are being developed and used. In this context, I am encouraged that the House of Lords Science and Technology Select Committee are investigating the use of nanotechnologies in the food sector, and am pleased to be able to provide evidence from my perspective as an expert in nanotechnology risk research and policy, and as the Chief Science Advisor to the Project on Emerging Nanotechnologies.

2. By way of background, the Project on Emerging Nanotechnologies is an initiative launched by the Washington DC-based Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology. Our goal is to take a long-term look at nanotechnologies; to identify gaps in the nanotechnology information, data, and oversight processes; and to develop practical strategies and approaches for closing those gaps and ensuring that the benefits of nanotechnologies will be realized. We aim to provide independent,

objective information and analysis that can help inform critical decisions affecting the development, use and commercialization of responsible nanotechnologies around the globe.

3. My own interest and involvement in nanomaterials stems from research I conducted at the University of Cambridge in the early 1990's, where I explored applying advanced electron microscopy to the characterization of atmospheric nanoparticles. Since then I have worked, published and lectured extensively on the potential benefits and risks of nanotechnologies, as well as broader issues relating to emerging technology and science policy. I was previously co-chair of the U.S. government working group coordinating interagency activities related to nanotechnology risk research and currently serve on a number of nanotechnology-related boards and committees, including the World Economic Forum Global Agenda Council on the Challenges of Nanotechnology and the Executive Committee of the International Council on Nanotechnology.

4. Since its inception in 2005, the Project on Emerging Nanotechnologies (PEN) has undertaken a number of activities relevant to this call for evidence, and I would like to summarize the pertinent points arising from these activities. I will also provide brief answers to some of the specific questions posed by the subcommittee, where they coincide with my particular areas of expertise and knowledge. Where relevant, I have provided links to further resources. However, given the brevity of this submission, I would ask that the subcommittee feel free to contact me directly on any points requiring further clarification. While this submission is written from a U.S. perspective, much of it will hold relevance for the safe use of nanotechnologies in food in the U.K.

5. **Regulatory Framework.** In 2006, PEN published a report by Michael R. Taylor—former Deputy Commissioner for Policy at the US Food and Drug Administration (FDA)—on regulating the products of nanotechnology from a FDA perspective.[1] Taylor's top-line recommendation for all FDA-regulated products—including food additives, food ingredients and food packaging—was that criteria need to be established for determining when substances are "new for legal and regulatory purposes," and "new for safety evaluation purposes." He expressed concern that, without such criteria (which still do not exist in the US), FDA and industry lack the means to identify and regulate nanoscale forms of materials that may present new risks due to novel nanostructure-dependent functionality. In particular, he was concerned over the (continuing) lack of clarity concerning how nanoscale versions of substances "Generally Regarded As Safe" should be regulated. The issues surrounding the regulation of nanotechnology-enabled food products by the U.S. FDA have been articulated repeatedly by Taylor.[2,3,4]

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[1] Taylor, M. (2006). *Regulating the products of nanotechnology: Does FDA have the tools it needs?*, PEN 5 Washington DC, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

[2] See footnote 1

[3] Public meeting on Nanotechnology Materials in FDA –Regulated Products Available at: http://www.nanotechproject.org/publications/archive/statement_michael_taylor_at_fda/

6. **Use of nanomaterials in food packaging.** It is currently unclear how the use of engineered nanomaterials in food packaging might impact on consumer safety, either through the release of material for packaging to food, through additional protection afforded by advanced packaging, or through feedback on the safety of food contained within packaging embedded with nanotechnology-enable sensors. In 2008, PEN published the findings of a study focused on assuring the safety of nanomaterials in food packaging—the result of a collaboration between PEN and the Grocery Manufacturers Association (GMA).[5] Using hypothetical scenarios, the study was based on a series of dialogues among experts and stakeholders from the U.S. government, industry and the public interest community exploring the legal and policy issues, as well as scientific and technical issues that might arise in ensuring the safe use of nanomaterials in food packaging. The study concluded that, while current regulatory approaches in the US provide a high level of consumer protection, the current state of scientific knowledge and need for case-by-case evaluation of emerging products requires greater scientific investment and innovation in order to satisfy established regulatory standards.

7. **Tracking consumer products (including food products) allegedly based on nanotechnology.** PEN maintains a publicly available on-line database of over 800 consumer products allegedly using nanotechnology in some form.[6] Entries are based on manufacturer claims, which are not validated independently, and are international in scope. As of March 6, 2009, there were 84 food-related items listed in the database. Nine of these are listed as used in cooking, and range from nanoscale silver particle-infused cutting boards and nanotechnology-enabled non-stick surfaces, to nano-silver sprays for disinfecting surfaces. 20 products are used for food storage—many of them using nanoscale silver particles as an antimicrobial agent. Forty-four listed products are categorized as dietary supplements, where the use of nanotechnology ranges from silver (and other metal) nanoparticles, to the use of nanoscale ingredients in enhancing uptake and effectiveness, to uses that are somewhat hard to fathom from the manufacturer-supplied information. Only three products listed are entered as "foods," and include oil that contains nanoencapsulated ingredients, a milkshake that uses a nanoscale silica-based compound to enhance the taste, and a tea that claims to use a non-disclosed form of nanotechnology to deliver beneficial components of the drink to consumers.

8. It is currently unknown how many nanotechnology-enabled food products are on the market that are not clearly identified. It is known that the food industry is carrying out research into using nanotechnology to improve manufacturing processes, increase food security and shelf life, and improve nutritional value and consumer satisfaction. And nanoscale materials such as fumed silica have been used in food products for many years. Yet the food industry is reticent to discuss

[4]Taylor, M. R. (2008). Assuring the safety of nanomaterials in food packaging: The regulatory process and key issues. Washington DC, Project on Emerging Nanotechnologies.

[5] see footnote 4

[6] An inventory of nanotechnology-based consumer products currently on the market. http://www.nanotechproject.org/inventories/consumer/

its use of the technology in public, and is currently under no obligation to reveal how nanotechnology is being used in products already on the market.

9. **Public perceptions.** Since 2006, PEN has commissioned annual phone surveys of public attitudes towards nanotechnology from Peter D. Hart Research Associates, Inc. The 2007 study, which included 1,014 participants, incorporated questions about attitudes towards the use of nanotechnology in food products.[7] Considering food in general, two thirds of the participants felt the food supply has become less safe in recent years. When asked about the specific use of nanotechnology in food related products and food, a large majority said they needed more information about the health risks and benefits associated with using the technology to enhance these products before they would use them. 13% of respondents said they would not use food storage products enhanced with nanotechnology and 73% said they would need more information before deciding to use them. In regards to food, 29% of adults claimed they would not purchase foods enhanced with nanotechnology, while another 62% said they would need more information before doing so. Adults who initially were more aware of nanotechnology were considerably more likely to report they would use both food storage products and foods enhanced with nanotechnology. Additionally, adults who had heard a significant amount about nanotechnology were nearly three times more likely than adults who had heard nothing to say they would use food storage products enhanced with nanotechnology, and were two and half times more likely to use foods enhanced with nanotechnology.

10. **Providing information on the use of engineered nanomaterials in foods.** There has been considerable discussion over the pros and cons of labeling nano-enabled products, although many of the discussions have been somewhat unclear on the purpose behind labeling or the information to be conveyed. Putting the contentious issue of "labeling" aside, information availability and communication is important for effective regulation and informed consumer choice. Regulators need clear information on ingredients and materials that may raise health and environmental concerns if not used appropriately. Manufacturers need clear information on the materials they handle and incorporate into their products, if they are to manage product safety effectively. And consumers need information on biologically relevant ingredients in the food products, if they are to be empowered to make informed choices on what they purchase and eat. The current state of science suggests that there are no underlying mechanisms of action that would justify blanket labeling of food items as containing engineered nanomaterials. Due to the diversity of engineered nanomaterials and their physical, chemical and biological behavior, such labeling would obfuscate evidence-based decision-making. However, current knowledge suggests that some engineered nanomaterials may have an effect on consumers that is

[7] Hart, Peter D. (2007) "Awareness of and Attitudes Toward Nanotechnology and Federal Regulatory Agencies" Peter D. Hart Research Associated, Washington DC, conducted on behalf of: Project on Emerging Nanotechnologies and The Woodrow Wilson International Center for Scholars Available at: http://www.nanotechproject.org/process/assets/files/5888/hart_presentation_2007analysis.pdf

associated with physical form as well as chemical make-up, and in these cases it would be helpful to identify the physical, as well as the chemical, form of ingredients. Such identification, whether available on the ingredients list or as supplemental publicly accessible information, would aid regulators and business as well as consumers.

11. **Next generation nanomaterials.** Many engineered nanomaterials currently being used in applications are nanoscale forms of materials that have been in use for some time. For instance, nanosilver consists of nanometer scale particles of metallic silver, and nano-titanium dioxide is a nanometer-scale form of a material used widely as a whitener in foods and other products. However, scientific and technological advances are enabling the formation of nanoscale materials with increasingly sophisticated forms and functions. These more sophisticated materials are often referred to as next generation nanomaterials. While no formal definitions exist for these nanomaterials, they can be typified by materials that are built up of complex arrangements of chemicals at the nanoscale, materials that change their behavior in the presence of different external stimuli (such as heat, light, pH, magnetic fields), materials that are designed to exhibit multiple functions (such as particles that can both deliver a drug to a predetermined site, then release it on demand), and materials that are designed to interact together—essentially to communicate—in complex ways. Such nanomaterials have more in common with complex products than simple chemicals, and raise questions over how their potential health and environmental impact should be evaluated and managed.

12. A number of "next generation" nanomaterials are under investigation for use in food products in the laboratory, although it is unclear whether any have been used in commercial products. Examples include materials designed to self-assemble into ingredient-carrying nanoscale capsules which can disassemble once in the body, and nanoscale sensors which are designed to be placed on or in food, where they can respond to their local environment and signal the presence of contaminants. Although the building blocks of these materials are invisible to the naked eye and may be transitory, they behave very differently from well-defined chemicals upon which many food regulations are based.

13. **Current state of scientific knowledge.** Although the state of scientific knowledge on engineered nanomaterials in food products is increasing, it is still low. In 2006 I published an assessment of the current state of knowledge, and a plan to fill in the knowledge gaps[8] (this was followed up later that year with a commentary in *Nature* laying out the greatest challenges to ensuring the safe use of nanotechnology across multiple areas of use[9]). At the time, I could not identify any research on the behavior of engineered nanomaterials in the gastrointestinal tract. While there is now a small amount of relevant research being conducted in

[8] Maynard, A. D. (2006). *Nanotechnology: A research strategy for addressing risk*, PEN 03 Washington DC, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

[9] Maynard, A. D., R. J. Aitken, T. Butz, V. Colvin, K. Donaldson, G. Oberdörster, M. A. Philbert, J. Ryan, A. Seaton, V. Stone, S. S. Tinkle, L. Tran, N. J. Walker and D. B. Warheit (2006). "Safe handling of nanotechnology." *Nature* **444**(16): 267-269.

this area, it remains at a low level. More generally, there are a number of current or recently completed research projects around the world that are concerned with the potential health impacts of engineered nanomaterials in food products. PEN maintains a public database of nanotechnology risk-related research, and searching this using the keyword "food" returns 23 projects.[10]

14. Over the past few years, there have been numerous expert reviews on the state of science regarding potential impacts of engineered nanomaterials.[11] In broad terms, these indicate that many nanomaterials demonstrate functionality that depends on their form as well as their chemical makeup; that different types of nanomaterials behave very differently; that some nanomaterials have the potential to cause harm by getting to normally inaccessible places, and/or demonstrating a biological activity that is associated with their form as well as their chemistry; that conventional toxicology assays may not provide a clear indication of nanomaterial toxicity; and that the potential harmfulness of nanomaterials may change with time and environment. There have been no known cases of health effects directly linked to exposure to engineered nanomaterials. However, there remain many knowledge gaps to understanding how new materials might cause harm, and how to avoid this harm.

15. Regarding food products, questions still requiring answers include: Can engineered nanomaterials in packaging migrate to food products and how can migration, and the resulting consequences, be evaluated? How is the potential toxicity of engineered nanomaterials best tested? How are engineered nanomaterials most appropriately measured and characterized? How do physical form and substance chemistry at the nanoscale influence biologically relevant behavior? How do changes in the physical structure and size of particles affect their absorption, dispersion, metabolism and excretion? Are increased dose rates resulting from decreased particle size and substance encapsulation important? Are people likely to be exposed to substances that can assemble into nanoscale materials in the body, and what might the health consequences be?

16. **Natural versus engineered nanomaterial risks.** Regarding food product safety, the important question is "how might something cause harm, and how can that be avoided", rather than "is this an engineered or a natural material"—the latter question having no direct bearing on safety. Natural nanoscale materials are present in food products, and there are no known cases of these being directly linked to health problems. Indeed, it can be argued that our bodies have evolved to manage and even take advantage of naturally occurring nanoscale substances. It is more relevant therefore to ask whether a new material—whether nanoscale or not—demonstrates properties that could lead to unconventional risks. From the current state of the science, there is a greater likelihood that materials specifically

[10] An inventory of current research involving nanotechnology health and environmental implications Available at: http://www.nanotechproject.org/inventories/ehs/

[11] E.g. Maynard, A., D. (2007). "Nanotechnology: The next big thing, or much ado about nothing?" *Ann. Occup. Hyg.* **51**: 1-12. Oberdörster, G., V. Stone and K. Donaldson (2007). "Toxicology of nanoparticles: A historical perspective." *Nanotoxicology* **1**(1): 2 - 25.

engineered to have nanoscale features will exhibit such novel properties. These include nanometer scale particles that are able to penetrate to regions of the body inaccessible to larger particles, increased dose rates associated with nanoscale materials, and mechanisms of action that are linked to the chemistry and physical form of specific engineered nanomaterials. Not all nanomaterials will be harmful. But there is a chance that some engineered nanomaterials will be more harmful than a conventional understanding indicates.

17. **Research funding.** Unanswered questions over the safe use of nanomaterials in food products currently far outstrip strategic investment in relevant research. In the U.S., investment in research projects specifically directed to understanding the health and environmental impacts of engineered nanomaterials is on the order of $20 million per year, although significantly more is being spent on research having some relevance to potential impacts. It is difficult to estimate the fraction of this investment dedicated to food-related research, but records in the PEN Nanotechnology Environment, Health and Safety Research Database suggest that it is something less than $1 million per year.[12]

18. Recently, the U.S. National Academies of Science criticized the U.S. government for not having a robust research strategy in place to address the safe use of nanotechnologies, and recommended the development of a national research strategy.[13] European funding for risk-relevant research appears to be outstripping the U.S.[14], although it is unclear whether current research will lead to answers that will support evidence-based decision-making on the safe use of nanotechnology in food products. My published assessments[15] indicate there remains a significant chasm between the research needed to support the safe use nanotechnologies, and research currently being funded.

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[12] See footnote 10

[13] Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, Committee on Toxicology, National Research Council. (2008). Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research. The National Academies Press, Washington, D.C.

[14] http://www.nanotechproject.org/news/archive/ehs-update/

[15] E.g. Maynard, A. D. (2008). United States House of Representatives Committee on Science & Technology Hearing on: The National Nanotechnology Initiative Amendments Act of 2008. Testimony of: Andrew D. Maynard, Ph.D. Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. April 16 2008., Washington DC, Project on Emerging Nanotechnologies.